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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,064	03/11/2004	Susanne Arney	10-18-4	5680

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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	PAPER NUMBER
3738	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,064	ARNEY ET AL.	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8,12,13,18-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bailey et al. (WO 02/64019). Bailey et al. disclose the stent is made of metal material (page 16). Please note that the Examiner is interpreting hydrophobic according to a known, common definition. *According to Dorland's Illustrated Medical Dictionary (2003), hydrophobic is defined as: not readily absorbing water.* Thus, since it is known metals do not absorb water, the surface of Bailey's stent must be hydrophobic. The surface is fully capable of having a hydrophobicity that has a contact angle greater than 90° when a drop of body fluid contacts it. Bailey additionally discloses a region of the stent has a plurality of microstructures that can include electronic components, page 5, lines 3-11. Another stent is also disclosed that describes an array of microstructures or grooves and hydrophobicity can be controlled in dynamic fashion, page 10, lines 17-33. The cellular response and its effect on the microstructure clearly effects hydrophobicity. Bailey et al. also disclose chemically active substances adhered to the stent and that a voltage or energy can be applied to the device from an ex vivo source, page 23, lines 5-15. Bailey additionally discloses controlled release of substances by electrical energy, page 23, lines 23-31. Please note that "isolated zones" is an arbitrary limitation and just like an elongate object, i.e. a stent has arbitrary ends, zones can be said to be present as

established in Figs. 1 and 3 since the means for applying electrical energy is spaced about the surface. Additionally fluid is capable of being suspended over the microstructures in a first state and then penetrate between the microstructures in a second state. It is also evident as seen in Fig. 4, that medicinal material is in the microstructures.

However, in the alternative Bailey does not explicitly state the surface has a contact angle greater than 90° when any drop of fluid contacts it. Please note that this is considered as a product by process limitation and that the product itself does not depend on the process for making it. It is within the skill of a material scientist to design a surface of a medical device to be compatible to the surroundings in which it is to be used. It would have been obvious to one of ordinary skill in the art to treat the surface to have a contact angle to fluid greater than 90° since such a modification only involves routine skill in the art. Because the Patent & Trademark Office does not have the testing facilities to provide factual evidence needed to establish that the claimed invention or subject matter is unobvious, the examiner properly shifts the burden to Applicants to show that unobvious differences exist, *Ex parte Phillips*, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93).

Claims 1,2,5-7,9-11 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Momma et al. (2005/27350). Fig. 2 shows a stent body **42** that includes an array microstructures **38** and control device in the form of a membrane **46** to vary hydrophobicity. The array of microstructures include surfaces of exposed and having chemically active substances in

two zones **52**, **54** adhered thereto capable of release at different times. Momma et al. disclose the stent is a metal and thus has a hydrophobic surface, paragraph 35. Please note that the Examiner is interpreting hydrophobic according to a known, common definition. *According to Dorland's Illustrated Medical Dictionary (2003), hydrophobic is defined as: not readily absorbing water.* Thus, since it is known metals do not absorb water, the surface of Momma's stent must be hydrophobic. The surface is fully capable of having a hydrophobicity that has a contact angle greater than 90° when a drop of body fluid contacts it. Momma additionally discloses the chemically active substances can be different, paragraphs 21,45. However, in the alternative Momma does not explicitly state the surface has a contact angle greater than 90° when any drop of fluid contacts it. Please note that this is considered as a product by process limitation and that the product itself does not depend on the process for making it. It is within the skill of a material scientist to design a surface of a medical device to be compatible to the surroundings in which it is to be used. It would have been obvious to one of ordinary skill in the art to treat the surface to have a contact angle to fluid greater than 90° since such a modification only involves routine skill in the art. Because the Patent & Trademark Office does not have the testing facilities to provide factual evidence needed to establish that the claimed invention or subject matter is unobvious, the examiner properly shifts the burden to Applicants to show that unobvious differences exist, *Ex parte Phillips*, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93).

Claims 1,2,5-7,15-17 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shastri et al. (2004/115239). Shastri et al. disclose an implant having a plurality of fibers or particles of nanosize placed on its surface, paragraph 48,49. Shastri also discloses the nano-material can be silicon (paragraphs 41,52) a semiconductor material. Shastri additionally discloses the implant can be a stent, paragraph 54. The nanostructures have a size within the range of 4μm to 20nm, paragraph 69. Shastri discloses chemically active substances can be used on the device with control devices (polymer materials), paragraphs 75,79,82,84. These include cells that change the surface properties or hydrophobicity. Shastri discloses (paragraph 87) properties modified or controlled, including wettability that the Examiner interprets to affect the hydrophobicity. However, in the alternative Shastri does not explicitly state the surface has a contact angle greater than 90° when any drop of fluid contacts it. Please note that this is considered as a product by process limitation and that the product itself does not depend on the process for making it. It is within the skill of a material scientist to design a surface of a medical device to be compatible to the surroundings in which it is to be used. It would have been obvious to one of ordinary skill in the art to treat the surface to have a contact angle to fluid greater than 90° since such a modification only involves routine skill in the art. Because the Patent & Trademark Office does not have the testing facilities to provide factual evidence needed to establish that the claimed invention or subject matter is unobvious, the examiner

properly shifts the burden to Applicants to show that unobvious differences exist, *Ex parte Phillips*, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93).

Claims 1,14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Oktay (2003/40791). Oktay shows (Fig. 10) a stent **1000** with an array of microstructures **1050**,**1060** on a region of the surface of the stent. Oktay discloses (paragraph 69) the stent structure is made of metal. Please note that the Examiner is interpreting hydrophobic according to a known, common definition. *According to Dorland's Illustrated Medical Dictionary (2003), hydrophobic is defined as: not readily absorbing water.* Thus, since it is known metals do not absorb water, the surface of Oktay's stent must be hydrophobic. The surface is fully capable of having a hydrophobicity that has a contact angle greater than 90° when a drop of body fluid contacts it. Oktay further illustrates (11A-11C) the stent includes electrically controllable structures **1040** for latching the edges of the tubular body.

However, in the alternative Oktay does not explicitly state the surface has a contact angle greater than 90° when any drop of fluid contacts it. Please note that this is considered as a product by process limitation and that the product itself does not depend on the process for making it. It is within the skill of a material scientist to design a surface of a medical device to be compatible to the surroundings in which it is to be used. It would have been obvious to one of ordinary skill in the art to treat the surface to have a contact angle to fluid greater than 90° since such a modification only involves routine skill in the art. Because the Patent & Trademark Office does not have the testing facilities to provide factual evidence needed to establish that the claimed invention or

subject matter is unobvious, the examiner properly shifts the burden to Applicants to show that unobvious differences exist, *Ex parte Phillips*, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93).

Claim Rejections - 35 USC § 103

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (WO 02/64019) in view of Momma et al. (2005/27350). Bailey et al. is explained supra. However, Bailey et al. fail to disclose different substances to be released into the implantation site. Momma et al. teach that different medicinal substances can be utilized to deliver to the implantation site for different purposes, paragraphs 21,45. It would have been obvious to one of ordinary skill in the art to incorporate different drugs on the stent as taught by Momma et al. in the stent of Bailey et al. such that it provides multiple therapeutic capabilities to encounter the biological responses of the body.

Response to Arguments

Applicant's arguments filed 1/22/08 have been fully considered but they are not persuasive. In applying the prior art, the claims should be construed to encompass all definitions that are consistent with applicant's use of the term. See Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202, 64 USPQ2d 1812, 1818 (Fed. Cir. 2002) and in this case, the Examiner has applied a well known, common definition of the term. It is appropriate to compare the meaning of terms given in technical dictionaries in order to

ascertain the accepted meaning of a term in the art. In re Barr, 444 F.2d 588, 170 USPQ 330 (CCPA 1971). Continuing with this issue, it should be noted that Applicant's representative attempts to assert that "hydrophobic" is defined with a special definition that is a limitation in the claims and mentioned in the specification. However, the limitation of "a contact angle greater than 90° when a fluid contacts the surface" is a description of the characteristics of a treated surface, it is not the definition for "hydrophobic". Where an Applicant chooses to be their own lexicographer to define terms and have a special meaning, they must set out the special definition explicitly and with "reasonable clarity, deliberateness, and precision" in the disclosure to give one of ordinary skill in the art notice of the change. In this application, there is no instance where Applicant states that when we say "hydrophobic" we mean this, the claimed limitation now alleged to mean "hydrophobic". Applicant's representative is misinterpreting what the disclosure describes. The examiner reviewed where Applicant described the new limitation of a contact angle of greater than 90° for fluid contacting the surface of the device. This is describing a characteristic of the surface as a result of Applicant's process of treating the surface with a voltage. Nowhere does it say that hydrophobicity means the claimed limitation. Thus, the Examiner was correct in interpreting the prior art with the understanding that materials that do not absorb water are hydrophobic. Applicants additionally submit a definition of wetting in an attempt to define hydrophobicity by using Wikipedia as a resource. However, it should be noted that Wikipedia is not an accepted resource to define a word or term. It is only an opinionated or attempt to describe how terms are used. Applicant then argues that the

references are not disclosing stent surfaces having hydrophobic characteristics as claimed. However, as mentioned above, the USPTO does not have the testing facilities to provide factual evidence needed to establish that the claimed invention or subject matter is unobvious, the examiner properly shifts the burden to Applicants to show that unobvious differences exist, *Ex parte Phillips*, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93). Applicant also argues that Shastri does not disclose the hydrophobic surface as claimed. However, as admitted by Applicant and in the attempt to define hydrophobic by a special definition with respect to wetting, Shastri clearly describes that wetting is controlled or affected at the surface and thus affects the hydrophobicity of the surface.

Applicant also attempts to argue claims defining "spatial zones" saying the prior art was not described. The terminology or limitation is relative and defines no structure to establish what defines a zone. The prior art clearly can have zones arbitrarily established since the claim sets forth no boundaries as to what defines a "zone". A zone is a broad area or region and can be said to be present when objects or elements defining structural elements are separated by spacing. Clearly, the prior art references can be said to include zones by the simple fact that the areas of where energy or spacing of the nanostructures are on the surface is not a continuous format, they establish spatial zones.

In response to applicant's argument that the Bailey and specifically the Momma reference fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the different substances are in

different zones and not in the same zone combined) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The teachings of Momma clearly disclose different substances as claimed and thus since the claims do not exclude the materials from being together it can be said that different zones have different substances since they include two different materials not the same.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738